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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHAFFER, RICHARD R

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3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/942,333	Applicant(s) ANGELUCCI ET AL.	
	Examiner Richard Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54,56,57 and 59-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54,56,57 and 59-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The amended drawing filed on January 4th, 2008 is acknowledged and accepted by the examiner. The previous drawing objection is hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 56, 57, 78 and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 56 and 78 recite a ratio of depth D to thickness T of approximately 4:1 to approximately 8:1.

Claim 57 and 79 recite a ratio of width W to thickness T of approximately 6:1 to approximately 12:1.

As described in the previous Office Action, applicant merely has support for ranges, not particular the particular ratios due to the lack of inherency of corresponding values as well as including non-supported values. For example the ratio of W to T, applicant has disclosed the width ranges between 10 and 11.5 mm with T ranging between 1 and 1.5 mm. There is no understandable connection between that range and

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6:1 to 12:1 for a ratio. Further, with regard D to T ratio, applicant has disclosed a range for D being 6.5 to 7.5 mm. 7.5 mm to 1 mm is not 8, and thus approximately 8 which includes 8 as well as numbers greater than 8. Likewise, for the low end of 6.5 mm to 1.5 mm, the ratio does not yield 4 or ratios less than 4.

Further, the ratios contain new matter due to including values outside of the those applicant has originally filed. For example, a width of 24 mm with thickness of 4 mm (neither of which supported by the specification) would have a ratio of 6:1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54, 56, 57, 59-76, 78 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirabayashi et al ("Contact of hydroxyapatite ...", Journal of Orthopaedic Science, 1999) in view of Boyle et al (US Patent 6,277,149) and Ford et al (US Patent 6,511,509).

Hirabayashi et al disclose an implant for maintaining a desired distance between first and second cut ends of a spinous process or lamina. The implant (**Figure 1b, page 265**) comprising a longitudinal axis (axis drawn through the center from left to right in the right picture of **Figure 1b**); a first end (left or right surface in **Figure 1b**); a second end (the opposite surface from the first end); an outer surface (top surface in **Figure 1b**); an inner surface (bottom surface in **Figure 1b**); the outer surface being longer than

the inner surface; and the first and second ends are angled at approximately 50-70 degrees with respect to the longitudinal axis of the implant.

Hirabayashi et al fail to disclose the implant being made of allograft, having a bore passing between the first and second ends, the first and second ends being demineralized, the specific values for a wall thickness, depth, and height, channels for receiving a surgical instrument, teeth on the first and second ends and a hole formed through the wall to allow the implant to be secured to cut bone.

Boyle et al teach (**Figures 1-21; Column 2, Lines 5-10; Column 2, Lines 40-50; Column 4, Lines 20-32; Column 5, Lines 5-22; and Column 5, Lines 63-67**) allograft implants formed from long bones that include a bore (which corresponds to the intramedullary canal) extending between two roughened ends. The ends (**Column 5, Lines 17-22**) are optionally demineralized in order to improve bone fusion as is well known in the art. Boyle et al further teach that slots and threaded bores are configured to mate with an implant insertion tool in order to facilitate insertion of the implant into the intervertebral space. It would have been obvious to one having ordinary skill in the art the time the invention was made to manufacture the implant of Hirabayashi et al from allograft harvested from long bones in order to avoid necrosis and pain at the iliac crest site as well as to improve bone fusion by utilizing natural bone with a demineralized outer shell, to provide roughened ends to increase fixation against bone, and to provide for slots and openings to allow engagement with an insertion tool to facilitate manipulation of the implant within the body. By manufacturing the bone according to

Boyle et al's teaching, the cross-sectional shape would be one of an ellipse, oval or circle.

Ford et al teach (**Figures 1A-2**) a textured bone allograft textured bone (also having an opening therethrough) having various embodiments of teeth extending to a height (**Column 2, Lines 7-15**) including 0.5 mm with the teeth angles (in **Figure 1A**) appearing to be about 45 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to consider making the roughened surface of the combination of Hirabayashi et al and Boyle et al as teeth as taught by Ford et al as a matter of mere substitution with predictable results to provide for the ability to help prevent the bone allograft to move relative to the bone.

It would have further been obvious to one having ordinary skill in the art at the time the invention was made to determine all of applicant's claimed ratios and ranges (D:T ratio falling within 4:1 to 8:1, W:T ratio falling within 6:1 to 12:1, thickness of 1.25 mm, W between 10 mm and 11.5 mm, D between 6.5 and 7.5 mm, demineralization depth of 2 mm, and an inner side length of 6.0 mm and 10 mm) since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In the instant case, Hirabayashi et al was solving the same problem as the instant case with laminoplasty.

Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirabayashi et al in view of Boyle et al and Ford et al (US Patent 6,511,509) and in further view of Kim et al (US Patent 5,980,572).

The combination of Hirabayashi et al, Boyle et al and Ford et al disclose and teach all of the claimed limitations except for an additional hole to allow the implant to be secured to the cut bone. Kim et al teach (**Column 4, Lines 40-45**) that through-holes (**12b and 13b, Figure 1**) allow for a nylon wire to fix the implant to the divided spines (cut bone in applicant's claim). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for additional holes to allow a nylon wire to pass through to provide for a secure initial fixation of the implant relative to the bone (by pressing surfaces of the implant against bone) for a laminoplasty procedure.

Response to Arguments

Applicant's arguments filed January 4th, 2008 have been fully considered but they are not persuasive.

With regard to the 35 U.S.C. 112, first paragraph rejections, as newly rejected due to amendment, claims 56 and 57 along with new claims 78 and 79 contain new matter due to values being included not previously supported by the measured ranges.

With regard to the 35 U.S.C. 103(a) rejection, applicant contends that the combination is improper due to the Boyle et al and Ford et al not being directed to a laminoplasty procedure. This distinction is not relevant to the teachings taken from those references. Boyle et al and Ford et al as described teaches using allograft implants which contain a bore due to the allograft site it was harvested from. The device being modified is the double door laminoplasty device of Hirabayashi et al. Thus the combined device would be appropriately sized and dimensioned as appreciated by one

having ordinary skill in the art (clearly Boyle et al and Ford et al are larger implants due to the implantation site and forces subjected to) for a laminoplasty implant being of allograft material and harvested from a long bone and thus containing a central bore.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733